REMARKS

This amendment is submitted in response to the Official Action mailed Dec 30, 2005. In view of the above claim amendments and the following remarks, reconsideration by the Examiner and allowance of the application is respectfully requested.

Claims 35, 37-39 and 41 have been amended to more particularly point out and distinctly claimed the subject matter that applicants regards as the invention. In particular, claim 35 has been amended to clarify that the treatment method is for treating a patient suffering from a condition of the arterial or venous vasculature capable of being modulated by inhibiting an activity of Factor Xa with a Factor Xa-inhibiting pyrrolopyridine compound. Claim 39 has been similarly amended to clarify that the composition is for treating a condition of the arterial or venous vasculature capable of being modulated by inhibiting an activity of Factor Xa and contains a therapeutically effective amount of a Factor Xa-inhibiting pyrrolopyridine. This is disclosed in the specification at page 1, lines 26-27 and does not introduce new matter to either claim.

Claims 35 and 39 have both also been amended to clarify that Z is bonded to a pyrrolopyrdine ring carbon atom. This is shown generally through out the specification and also does not introduce new matter. Claims 35 and 39 have also been amended to claim pharmaceutically acceptable salts, N-oxides, hydrates and solvates of the pyrrolopyridine compound. This was a limitation of original claim 1 and therefore also does not introduce new matter. Claims 35 and 39 have also been amended to correct various typographical errors without introducing new matter. Finally, claim 39 has further been amended to clarify that the additional agents of the pharmaceutical composition are formulated in a separate or combined formulation with the pyrrolopyridine compound. This is disclosed in the specification at page 173 lines 28-30 and also does not introduce new matter.

In addition, claims 37 and 41 have been amended to clarify that the direct thrombin inhibitors include pharmaceutically acceptable salts and prodrugs thereof. This is disclosed in the specification in the last line of page 172 and does not introduce new matter. Finally, claim 38 has been amended to clarify that hirudin includes hirudin derivatives and analogs thereof. This is disclosed in the specification at page 173, lines 3-4, and also does not introduce new matter.

In view of the above claim amendments, the within application is believed to be in condition for allowance. Reconsideration of the rejections made by the Examiner is therefore respectfully requested.

Turning to the Official Action, claims 35-41 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. In particular, the Examiner considered the language "a physiological disorder capable of being modulated by inhibiting an activity of Factor Xa" in claim 35 to be indefinite because it reads on disorders with too little clotting and disorders with too much clotting, and because the specification also associated Factor Xa "with more diseases than just blood coagulation." Claims 35 and 39 were also considered indefinite by the Examiner for reciting the positions of Z as "positions 2-7" on the pyrrolopyridine ring when the specification did not number the pyrrolopyridine ring consistent with the way recognized by the art. The Examiner also considered claim 39 indefinite because it was not clear if the additional agents were formulated in the same composition with the pyrrolopyridine compound, or if the additional agents were in a separate formulation. Finally, the Examiner rejected claim 38 for lacking antecedent basis because it depends from claim 35 but recites "prodrugs, derivatives and analogs thereof," which are not recited in claim 35. These rejections are respectfully traversed in view of the above claim amendments for the reasons set forth hereinafter.

Claim 35 has been amended to clarify that the claimed method in treating a patient suffering from a condition of the arterial or venous vasculature capable of being modulated by inhibiting an activity of Factor Xa. The conditions intended for treatment are readily identified by one having ordinary skill in the art. The diseases intended for treatment by the method of claim 35 are now clear. By amending claim 35 in this manner, this portion of the rejection of claims 35-38 as indefinite under 35 U.S.C. § 112, second paragraph has been traversed.

Claim 35 has also been amended, as well as claim 39, to clarify that Z is bonded to a pyrrolopyridine ring carbon atom, instead of referring to a numbered ring position. The ring atoms to which Z may be bonded are now clear to one of ordinary skill in the art. By amend-

ing claims 35 and 39 in this manner, this portion of the rejection of claims 35-41 as indefinite under 35 U.S.C. § 112, second paragraph has also been traversed.

Claim 39 has also been amended to clarify that the additional agents of the pharmaceutical composition are in a separate or combined formulation with the pyrrolopyridine compound. The metes and bounds of this feature of the claimed pharmaceutical composition are now cleared to one of ordinary skill of the art. By amending claim 39 in this manner this portion of the rejection of claims 39-41 as indefinite under 35 U.S.C. §112, second paragraph has been traversed.

Regarding the rejection of claim 38, this claim depends directly from claim 37 and only indirectly from claim 35. A review of the specification reveals that pharmaceutically acceptable salts and prodrugs refer to the direct thrombin inhibitors of claim 37, and the derivates and analogs refers to hirudin. Accordingly, claims 37 and 38 have been amended so they are now consistent with the specification. Claim 41, which corresponds to claim 37, has been similarly amended.

While claims 35 and 36, from which claims 37 and 38 directly or indirectly depend, do not recite pharmaceutically acceptable salt, prodrugs, derivates and analogs, the direct thrombin inhibiting agents and inhibitors referred to in claims 35 and claims 36 are generic to pharmaceutically acceptable salts and prodrugs of direct thrombin inhibitors. Likewise, hirudin and hirudin derivatives and analogs thereof are also species of the direct thrombin inhibiting agents and inhibitors of claims 35-37.

Amended claims 37 and 38 therefore do not lack antecedent basis for the recited claimed terms. This portion of the indefiniteness rejection under 35 U.S.C. § 112, second paragraph has thus also been traversed.

By amending claims 35, 37-39 and 41 to clarify the conditions being treated, the positioning of the Z group on the pyrrolopyridine ring, the additional agents for which pharmaceutically acceptable salts, prodrugs, derivatives and analogs thereof are being claimed, and the formulation of the pyrrolopyridine compound and additional agent in either separate or combined formulations, this rejection of claims 35-41 as indefinite under 35

U.S.C. § 112, second paragraph has thus been overcome. Reconsideration by the Examiner and withdrawal of this rejection is therefore respectfully requested.

Next, claims 35-41 were rejected under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement. In particular, the Examiner considered the recited combinations of compounds for treating "a physiological disorder capable of being modulated by inhibiting an activity of Factor Xa," which include more than anticoagulant therapy, to be "unduly broad." The Examiner also considered claim 39 to be unduly broad because it recited the same combination of pyrrolopyridine compounds and additional agents as that recited in claim 35. The Examiner considered the claimed combination "unduly broad" without regard to the indication that the combination was intended to treat. This rejection is respectfully traversed in view of the above claim amendments for the reasons set forth hereinafter.

The breadth of the independent claims are now limited to a scope for which adequate direction and guidance is presented in the specification in view of the state of the art related to Factor Xa inhibitors. Regardless of the activity other pyrrollopyridine compounds have, the pyrrolidinone-pyrrolopyridine molecular core identified by the Examiner is reported by Applicant to have Factor Xa inhibiting activity. If one skilled in the art, based on knowledge of compounds having similar physiological or biological activity, would be able to discern an appropriate dosage or method of use without undue experimentation, this would be sufficient to satisfy 35 U.S.C. § 112, first paragraph. (See MPEP §2164.01(c)).

That is, the enablement of how to practice the claimed treatment method with the claimed pharmaceutical compositions is not evaluated relative to compounds with similar structures, it is evaluated relative to compounds with similar activity. For the treatment of Factor Xa modulated conditions of the arterial or venous vasculature, undue experimentation is not required for one of ordinary skill in the art guided by the present specification to apply the presently claimed pharmaceutical composition to the presently claimed treatment method by comparison of the inhibitory activities of the inventive compositions to other known Factor Xa inhibitor compositions. Amended claim 35 is thus directed to treatment methods adequately enabled by the teachings of the specification viewed in the context of the Factor

Xa inhibitor state of the art. In view of the Factor Xa state of the art, amended pharmaceutical composition claim 39 is adequately enabled as well.

Claims 35-41 therefore satisfy the enablement requirements of 35 U.S.C. §112, first paragraph as it relates to Factor Xa inhibiting compositions and treatment methods. By amending claim 35 so it is now directed to a method for treating a patient suffering from a Factor Xa modulated condition of the arterial or venous vasculature, and similarly amending claim 39, this rejection of claim 35-41 for lack of enablement under 35 U.S.C. §112, first paragraph has thus been overcome. Reconsideration by the Examiner and withdrawl of this rejection is therefore respectfully requested.

In view of the above claim amendments and the foregoing remarks this application is now in condition for allowance. Reconsideration is respectfully requested. The Examiner is requested to call the undersigned at the telephone number indicated below if there any issues remaining in this application to be resolved. Finally, if there are any additional charges in connection with this response, the Examiner is authorized to charge Applicants' Deposit Account No. 19-5425 therefor.

Respectfully submitted,

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